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EXAMINER	
WANG, G	

ART UNIT	PAPER NUMBER
1812	

LEGAL AFFAIRS
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DATE MAILED: 01/17/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12-19-91 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-23 are pending in the application.

   Of the above, claims 1-10 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 11-23 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under .U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1812.

Applicant's election of group II, claims 11-23 in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Claims 1-10 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention. Election was made without traverse in Paper No. 16.

Claims 11-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims noted supra are vague and indefinite in the recitation of "PACE" in claim 11, line 2 and claim 19, line 3. The abbreviation of "PACE" should be spelled out in a complete phrase at the first appearance in the claim because it could stand for subject matter which may not be related to the claimed invention.

The claims noted supra are vague and indefinite in the recitation of "a nucleotide sequence" in claim 11, line 2 and lines 5-6; in claim 19, line 2 and lines 5-6; and the recitation

of "the nucleotide sequence" in claim 11, lines 4-5 and lines 8-9; in claim 19, lines 4-5 and lines 8-9; and the recitation of "a DNA sequence" in claim 11, lines 1-2 and line 5; in claim 19, lines 1-2 and line 5 because it is confusing to use the same terminology for different identities of DNA molecules.

Claims 11-18 are vague and indefinite in the recitation of "a DNA sequence" in claim 11, lines 1-2 and line 5 because it is confusing whether these two DNA sequences are in a recombinant DNA molecule or separate DNA molecule.

The claims noted supra are vague and indefinite in the recitation of "the precursor" in claim 1, line 6 and claim 19, line 6 because of the lack of antecedent basis.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.55 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 11-23 are rejected under 35 U.S.C. § 103 as being unpatentable over van den Ouweland et al. in view of Kaufman et al. or Hagen et al..

van den Ouweland et al. disclose a mammalian precursor protein processing enzyme which has 100 % homology to the sequence of a paired basic amino acid cleaving enzyme (PACE) as indicated in claims 11 and 19. Kaufman et al. disclose high yield production of active factor IX in a Chinese Hamster Ovary (CHO) cell line transfected with factor IX cDNA in medium containing vitamin K to produce biologically active blood coagulation proteins and plasma proteins containing gamma-carboxyglutamic acid (see claims 1-6, and column 2). Hagen et al. disclose methods for producing proteins which require gamma-carboxylation for biological activity for blood coagulation mediated by factor VII in mammalian cells transfected with a recombinant DNA molecule containing the first nucleotide sequence of factor VII with a calcium binding domain and the second nucleotide sequence with a serine protease activity (see claims 1-32 and columns 7-8). Thus, with van den Ouweland et al. providing the motivation of a mammalian precursor protein processing enzyme with cleaving activity at the paired basic amino acid sequences, and with Kaufman et al. or Hagen et al.

providing methods for expression of factor VII or factor IX in mammalian cells transfected with a recombinant DNA molecule to produce biologically active proteins by cleaving paired basic amino acid sequences, it would have been obvious at the time of the invention to one of ordinary skill in the art to obtain the claimed invention in the instant application as suggested by the prior art. Therefore, the invention as a whole was prima facie obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Gian Wang, Ph.D. whose telephone number is (703) 308-3993.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID L. LACEY
SUPERVISOR PRIMARY EXAMINER
ART UNIT 1812

1/9/92

G. W.
Gian Wang
January 8, 1992